PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Please cancel claims 1-81 and add claims 82-105 as follows:

1-81. (Canceled)

82. (New) A stable pharmaceutical formulation comprising:

a non-aqueous granulate comprising:

at least one cyclic amino acid which is susceptible to formation of a

lactam:

at least 20 ppm of an anion of a mineral acid, based on the weight of said at least one cyclic amino acid; and

at least one stabilizer to inhibit the formation of said lactam, wherein said formulation contains less than 2% by weight of a degradation product of the amino acid after being maintained for 3 months at 40 degrees Centigrade and 75 % relative humidity.

- 83. (New) The formulation of claim 82 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, or polysorbates.
- 84. (New) The formulation of claim 82 wherein said stabilizer is ethanol.
- 85. (New) The formulation of claim 82 wherein said cyclic amino acid is gabapentin.
- 86. (New) The formulation of claim 82 wherein the anion of a mineral acid is chloride ions.
- 87. (New) The formulation of claim 82 wherein said non-aqueous granulate is prepared by dispersing said at least one cyclic amino acid in said at least one stabilizer;

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contacting a mineral acid with said at least one stabilizer and said at least one cyclic amino acid in an amount sufficient to provide at least 20 ppm anion of a mineral acid, based on the weight of said at least one amino acid; and

substantially completely removing said at least one stabilizer.

- 88. (New) The formulation of claim 82 wherein said formulation is a unit dosage form.
- 89. (New) The formulation of claim 82 wherein said at least one cyclic amino acid is susceptible to formation of a lactam via a dehydration reaction that causes cyclication of said at least one amino acid to a lactam.
- 90. (New) The formulation of claim 82 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.
- 91. (New) The formulation of claim 82 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 60 degrees Centigrade and 75% relative humidity.
- 92. (New) A method of removing lactam from a cyclic amino acid comprising the steps of:
 dispersing said amino acid in a non-aqueous granulating liquid;

contacting said non-aqueous granulating liquid with a mineral acid in an amount sufficient to provide more than 20 ppm of anion of said mineral acid, based on the weight of said cyclic amino acid; and

substantially completely removing said non-aqueous granulating liquid.

93. (New) The method of claim 92 wherein said formulation after said removing step contains less than 2% by weight of lactam after being maintained for 3 months at 60 degrees Centigrade and 75 % relative humidity.

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- 94. (New) The formulation of claim 92 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.
- 95. (New) The formulation of claim 92 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 40 degrees Centigrade and 75% relative humidity.
- 96. (New) A stable pharmaceutical formulation comprising:
 - (i) an active agent consisting essentially of gabapentin in the free amino acid, crystalline anhydrous form; less than 0.5% by weight of its corresponding lactam; and greater than 20 ppm of an anion of a mineral acid;
 - (ii) at least one stabilizer to inhibit formation of said lactam; and
 - (iii) one or more pharmaceutically acceptable adjuvants;

wherein said formulation contains less than 2% by weight of a degradation product of the amino acid after being maintained for 3 months at 40 degrees Centigrade and 75 % relative humidity.

- 97. (New) The formulation of claim 96 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, or polysorbates.
- 98. (New) The formulation of claim 96 wherein said stabilizer is ethanol.
- 99. (New) The formulation of claim 96 wherein said anion of a mineral acid is chloride ions.
- 100. (New) The formulation of claim 96 wherein said active agent is prepared by dispersing said gabapentin in said at least one stabilizer;

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contacting said mineral acid with said at least one stabilizer and said gabapentin in an amount sufficient to provide more than 20 ppm anion of a mineral acid, based on the weight of said gabapentin; and

substantially completely removing said at least one stabilizer.

101. (New) The formulation of claim 96 wherein said formulation is a unit dosage form.

102. (New) The formulation of claim 96 wherein said gabapentin is susceptible to formation of a lactam via a dehydration reaction that causes cyclization of said at least one amino acid to a lactam.

103. (New) The formulation of claim 96 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.

104. (New) The formulation of claim 96 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 60 degrees Centigrade and 75% relative humidity.

105. (New) The formulation of claim 96 wherein substantially completely removed is at least about 90% by weight.

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